

Supplementary Materials

Telbivudine Plus Adefovir Versus Lamivudine Plus Adefovir for Lamivudine-Resistant Chronic Hepatitis B: TeSLA Randomized Trial

Methods

1. Sample size calculation

The virological responses found through literature review were approximately 33% for LMV+ADV in LMV resistant and 75% for L-dT in treatment naïve chronic hepatitis B patients, respectively (1, 2). We presumed the virologic response rate of 75% for L-dT+ADV in LMV resistant patients as there was no previous data.

We calculated the sample size using PASS 2008, setting alpha-error to 0.05 and power to 0.8, so that obtained 21 subjects to each group. Considering the dropout rate of 30%, 30 subjects were assigned to each group, and a total of 60 subjects were suggested to enroll. However, as the study progressed, there was few dropout, so the enrollment was closed with 43 subjects.

References

1. Peters MG, Hann HW, Martin P, Heathcote EJ, Buggisch P, Rubin R, et al. Adefovir dipivoxil alone or in combination with lamivudine in patients with lamivudine-resistant chronic hepatitis B. *Gastroenterology*. 2004;126(1):91-101. doi:10.1053/j.gastro.2003.10.051. [PubMed:14699491].
2. Lai CL, Gane E, Liaw YF, Hsu CW, Thongsawat S, Wang Y, et al. Telbivudine versus lamivudine in patients with chronic hepatitis B. *N Engl J Med*. 2007;357(25):2576-88. doi:10.1056/NEJMoa066422. [PubMed:18094378].